IFW

Docket No.: 0020-5461PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Noriyuki SATO et al.

Application No.: 10/563,916 | Confirmation No.: 5447

Filed: January 10, 2006 | Art Unit: N/A

For: HLA-A24 BINDING CANCER ANTIGEN PEPTIDE DERIVED FROM LIVIN | Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Subsequent to the filing of the above-identified application on January 10, 2006, attached hereto is an English translation of the International Preliminary Report on Patentability (Form PCT/IB/338 and 373) and of the Written Opinion of the International Searching Authority (Form PCT/ISA/237) that should be made of record in the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or to credit any overpayment to Deposit Account No. 02-2448 for any

additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: July 26, 2006

Respectfully submitted,

By _____

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Attachment(s)

PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44*bis*.3(c) and 72.2)

To:

ISOBE, Yutaka
Intellectual Property (Kasugade)
Dainippon Sumitomo Pharma Co., Ltd.
1-98, Kasugadenaka 3-chome
Konohana-ku, Osaka-shi
Osaka 5540022
JAPON

受信
18.6.12
知的財産部

Date of mailing *(day/month/year)*	
01 June 2006 (01.06.2006)	
Applicant's or agent's file reference 533726	**IMPORTANT NOTIFICATION**
International application No. PCT/JP2004/010008	International filing date *(day/month/year)* 07 July 2004 (07.07.2004)
Applicant SATO, Noriyuki et al	

1. **Transmittal of the translation to the applicant.**

☑ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).

☐ The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. **Transmittal of the copy of the translation to the designated or elected Offices.**

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. **Reminder regarding translation into (one of) the official language(s) of the elected Office(s).**

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Yoshiko Kuwahara
Facsimile No.+41 22 740 14 35	Facsimile No.+41 22 338 90 90

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44*bis*)

Applicant's or agent's file reference 533726	**FOR FURTHER ACTION**	See item 4 below
International application No. PCT/JP2004/010008	International filing date *(day/month/year)* 07 July 2004 (07.07.2004)	Priority date *(day/month/year)* 11 July 2003 (11.07.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant SATO, Noriyuki		

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 *bis*.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☒	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☒	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☐	Box No. VII	Certain defects in the international application
☐	Box No. VIII	Certain observations on the international application

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44*bis*.3(c) and 93*bis*.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44*bis* .2).

	Date of issuance of this report 22 May 2006 (22.05.2006)
The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Facsimile No. +41 22 740 14 35	Authorized officer Yoshiko Kuwahara Telephone No. +41 22 338 90 90

Form PCT/IB/373 (January 2004)

PATENT COOPERATION TREATY

TRANSLATION

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43*bis*.1)

	Date of mailing *(day/month/year)*
Applicant's or agent's file reference 533726	FOR FURTHER ACTION See paragraph 2 below

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/JP2004/010008	07.07.2004	11.07.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant
SATO, Noriyuki

1. This opinion contains indications relating to the following items:

- ☒ Box No. I — Basis of the opinion
- ☐ Box No. II — Priority
- ☒ Box No. III — Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV — Lack of unity of invention
- ☒ Box No. V — Reasoned statement under Rule 43*bis*.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI — Certain documents cited
- ☐ Box No. VII — Certain defects in the international application
- ☐ Box No. VIII — Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1*bis*(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP Facsimile No.	Authorized officer Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/010008

Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

☒ a sequence listing

☐ table(s) related to the sequence listing

b. format of material

☐ in written format

☒ in computer readable form

c. time of filing/furnishing

☐ contained in the international application as filed.

☒ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/010008

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 1-26 (those parts not pertaining to SEQ ID NOS 25 and 33)

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 1-26 (those parts not pertaining to SEQ ID NOS 25 and 33)

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form
- ☐ has not been furnished
- ☐ does not comply with the standard

the computer readable form
- ☐ has not been furnished
- ☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/010008

Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has:

   ☐ paid additional fees

   ☐ paid additional fees under protest

   ☒ not paid additional fees

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with

   ☒ not complied with for the following reasons:

Claim 1 describes an invention relating to a peptide which consists of a sequence of 8 to 11 continuous amino acids in the amino acid sequence of livin represented by SEQ ID NO 1, and which couples with antigen HLA-A24 so as to be recognized by CTL cells.

In claim 2, an invention relating to the peptide according to claim 1 which contains an amino acid sequence represented by any of SEQ ID NOS 2-59 is described alternatively in a single claim.

It appears that the invention described in claim 2 has been described alternatively in a single claim by the applicants in this case as having a technical relationship with a peptide which consists of a sequence of 8 to 11 continuous amino acids in the amino acid sequence of livin represented by SEQ ID NO 1, and which couples with antigen HLA-A24 so as to be recognized by CTL cells.

However, a peptide such as this had already been publicly known as of the priority date for this application as prior art in *Proc. Natl. Acad. Sci. USA* (18 March 2003) Vol. 100, No. 6, pp. 3398-3403 (see in particular page 3399, JS34, JS90, etc.).

Thus, the alternative description of the international application in this case clearly does not possess novelty over prior art.

Consequently, there does not appear to be a technical relationship among the inventions of the claims involving one or more of the same or corresponding "special technical features".

As a result, the inventions of the application in this case do not fulfil the requirement of unity of invention in accordance with PCT Rule 13.

(Moreover, the peptides associated with SEQ ID NOS 2-59 in the present invention appear to represent 31 different inventions because no common structures are shared by the sequences of SEQ ID NOS 2-3 and 9; 4 and 22; 5; 6 and 54; 7-10 and 53; 11; 12 and 16, or 45; 13-14, 34 or 41; 15; 17 and 44; 18 and 59; 19 and 38; 20, 42 or 47; 21 and 37; 23 and 35; 24 and 39; 25 and 33; 26; 27 and 55; 28 and 56; 29 and 51; 30 and 57; 31; 32 and 58; 36; 40; 43; 46; 48; and 52.)

4. Consequently, this opinion has been established in respect of the following parts of the international application:

   ☐ all parts

   ☒ the parts relating to claims Nos. 1-26 (those parts pertaining to SEQ ID NOS 25 and 33)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/JP2004/010008

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	3-6, 9-26	YES
	Claims	1-2, 7-8	NO
Inventive step (IS)	Claims		YES
	Claims	1-26	NO
Industrial applicability (IA)	Claims	1-26	YES
	Claims		NO

2. Citations and explanations:

Document 1: Schmollinger, JC, et al., "Melanoma inhibitor of apoptosis protein (ML-IAP) is a target for immune-mediated tumor destruction," *Proc. Natl. Acad Sci. USA* (18 March 2003), Vol. 100, No. 6, pp. 3398-3403
Document 2: Kasof, GM, et al., "Livin, a novel inhibitor of apoptosis protein family member," *J. Biol. Chem.* (2001) Vol. 276, No. 5, pp. 3238-3246
Document 3: JP 2002-316998 A (Hokkaido Technology Licensing Office Co., Ltd.)
Document 4: JP 2002-284797 A (Hokkaido Technology Licensing Office Co., Ltd.)

The inventions of claims 1-2 and 7-8 do not appear to be novel or to involve an inventive step based on document 1 cited in the ISR.

Document 1 describes peptides having amino acid sequences identical to those of SEQ ID NOS 25 and 33 in the present application.

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: Box V

The inventions of claims 1-26 do not appear to involve an inventive step over documents 2-4 cited in the ISR.

Document 2 describes livin having an amino acid sequence identical to that of SEQ ID NO 1 in the present application.

The difference is that while these claims relate to peptides which have 8-11 amino acids derived from livin and which couple with antigen HLA-A24 so as to be recognized by cytotoxic T cells, the invention described in document 2 relates to full-length livin.

This difference is investigated here. Document 3 describes a peptide derived from the cancer antigen peptide rikavarin and consisting of 9 or 10 amino acids, and also describes that this peptide couples with antigen HLA-A24 to induce cytotoxic T cells that target cancer cells. It also describes the use of the cytotoxic T cells thus induced as an anti-cancer drug, cancer vaccine or other drug composition.

Document 4 describes a peptide comprising part of the amino acid sequence of survivin (which belongs to the same IAP family as livin) and consisting of 9 or 10 amino acids, and also describes that this peptide couples with antigen HLA-A24 to induce cytotoxic T cells that target cancer cells. It also describes the use of the cytotoxic T cells thus induced as an anti-cancer drug, cancer vaccine or other drug composition.

Since the inventions described in documents 2-4 all relate to cancer antigen peptides, it would be easy for a person skilled in the art to conceive, based on the descriptions of documents 3-4, of analyzing that site on the livin of the invention described in document 2 that couples with antigen HLA-A24 so as to be recognized by cytotoxic T cells, thus obtaining such a fragment. Moreover, the effects achieved are not found to be so remarkable that they could not be predicted.

Moreover, manufacturing a mutant having an amino acid sequence differing from that of a natural peptide having a specific amino acid sequence, obtaining antibodies to that peptide, and using it in detection and in the drugs for diagnosis of diseases associated with that peptide are all well-known technologies which do not present any special technical difficulties.